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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,970	04/15/2004	Scott J. Gerondale	3011	7529

7590 12/08/2006

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EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,970	GERONDALE ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. §.119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/18/04; 4/15/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 8/18/2004 and 4/15/2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

2. The disclosure is objected to because of the following informalities:

3. On pg 7, ln 14, "shell 19" should be "shell 18". The shell is disclosed elsewhere in the specification as being (18) and no reference number 19 is shown in the drawings.

4. On pg 7, ln 6, "pivot 72" should be "pivot 56". The pivot is disclosed elsewhere in the specification as being (56) and no reference number 72 is shown in the drawings.

Appropriate correction is required.

5. The use of the trademark BOTOX^{tm} has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Drawings

6. The drawings are objected to because reference numbers "19" and "72 are note shown in the drawings (see above discussion). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should

include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

7. Claim 6 is objected to because of the following informalities: Claim 6 recites the limitation "BOTOX^{tm}" which is a trademark. The Examiner strongly suggests changing the limitation to the generic terminology, namely "Botulinum toxin". Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4, 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Butuzov et al (5891106). Butuzov et al discloses a controlled volume injection/aspiration device comprising: a syringe having a body (17), needle (12), and piston (18); a shell (2) receiving the syringe; a plunger rack (4; Fig 1) slidably disposed within said shell; a manually operated control (7, Fig 2) moving said plunger rack in a stepwise forward direction causing piston to eject discrete doses of medication (Fig 2-3; Summary, col 4, lns 21-col 5, lns 39) and in a stepwise reverse direction causing piston to aspirate discrete quantities of fluid (Fig 2-3; Summary; col 4, lns 21-col 5, lns 39; col 2, lns 14-19); a window (20; Fig 2) for view aspirated fluid; the control comprising an injecting pawl (5; Fig 2-3; Summary, col 4, lns 21-col 5, lns 39) that engages the plunger rack in a stepwise forward direction and disengages the rack upon movement in a stepwise reverse direction; the control comprising a withdrawing pawl (6; Fig 2-3; Summary, col 4, lns 21-col 5, lns 39) that engages the plunger rack in a stepwise reverse direction and disengages the rack upon movement in a stepwise forward direction; the control being configured for finger operation (Fig 2-3); and the syringe being removable from the shell (col 5, lns 28-39).

10. Claims 1-4, 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by H. Sturtz (2892457). H. Sturtz discloses a controlled volume injection/aspiration device comprising: a syringe having a body (19), needle (Fig 1), and piston (20; Fig 1); a shell (16, 26, 32) receiving the syringe; a plunger rack (35; Fig 3) slidably disposed within said shell; a manually operated control (65; col 1, lns 15-18, 38-48; col 2, lns 17-73, col 3, lns 1-10, 21-35, 60-69) moving said plunger rack in a stepwise forward direction

causing piston to eject discrete doses of medication (col 2, lns 17-73, col 3, lns 1-10, 21-35, 60-69; esp. col 3, lns 20-35) and in a stepwise reverse direction causing piston to aspirate discrete quantities of fluid (col 2, lns 17-73, col 3, lns 1-10, 21-35, 60-69; esp col 2, lns 65-col 2, lns 9); a window (Fig 1) for view aspirated fluid; the control comprising an injecting pawl (34) that engages the plunger rack in a stepwise forward direction and disengages the rack upon movement in a stepwise reverse direction; the control comprising a withdrawing pawl (53) that engages the plunger rack in a stepwise reverse direction and disengages the rack upon movement in a stepwise forward direction; the control being configured for finger operation (Fig 1); and the syringe being removable from the shell (Fig 1, col 3, lns 60-69).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Butuzov et al. Butuzov et al discloses the invention substantially as claimed except for expressly disclosing the control is configured to ejecting medicament in the range between 5 microliters and 1 milliliter. Butuzov et al is silent as to then exact medicament dosage injected/withdrawn for each prawl. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the control as taught by Butuzov et al with a capability range between 5 microliters and 1 milliliter since it was

well known in the art that injection amounts of analgesia is used to provide injection amounts on a drop by drop basis that corresponds to a range between 5 microliters and 1 milliliter because the exact dosage is extremely important to prevent overdosing (col 1, lns 22-53).

13. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over H. Sturtz. H. Sturtz discloses the invention substantially as claimed except for expressly disclosing the control is configured to ejecting medicament in the range between 5 microliters and 1 milliliter. H. Strutz is silent as to then exact medicament dosage injected/withdrawn for each prawl. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the control as taught by H. Sturtz with a capability range between 5 microliters and 1 milliliter since it was well known in the art that injection by hypodermic syringes are often used to provide injection amounts on a drop by drop basis that corresponds to a range between 5 microliters and 1 milliliter because with many medicaments the proper dosage is extremely important to prevent overdosing.

14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Butuzov et al in view of Pasricha et al. Butuzov et al discloses the invention substantially as claimed except for expressly disclosing the medicament is BOTOX. Pasricha et al teaches that it is known to have the medicament be BOTOX for the purpose of injecting a neurotoxin, such as BOTOX, to inhibit neurotransmitter release from nerve terminals to treat and alleviate symptoms of certain diseases, such as those arising from chronic smooth muscle disorders. It would have been obvious to one having ordinary skill in the

art at the time the invention was made to modify the medicament as taught by Butuzov et al with the BOTOX as taught by Pasricha et al for the purpose of injecting a neurotoxin, such as BOTOX, to inhibit neurotransmitter release from nerve terminals to treat and alleviate symptoms of certain diseases, such as those arising from chronic smooth muscle disorders.

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over H. Sturtz in view of Pasricha et al. H. Sturtz discloses the invention substantially as claimed except for expressly disclosing the medicament is BOTOX. Pasricha et al teaches that it is known to have the medicament be BOTOX for the purpose of injecting a neurotoxin, such as BOTOX, to inhibit neurotransmitter release from nerve terminals to treat and alleviate symptoms of certain diseases, such as those arising from chronic smooth muscle disorders. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medicament as taught by H. Sturtz with the BOTOX as taught by Pasricha et al for the purpose of injecting a neurotoxin, such as BOTOX, to inhibit neurotransmitter release from nerve terminals to treat and alleviate symptoms of certain diseases, such as those arising from chronic smooth muscle disorders.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons